Improving the mental health of offenders in primary care

Strategies to enhance social inclusion are as important as medical interventions

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RESEARCH p 303

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According to a recent MORI poll, doctors are viewed by the public as the most trusted professionals; more than 90% of the public trust doctors to be truthful and 80% view them as helpful.[1] However, a qualitative study reported in this week's *BMJ* by Howerton and colleagues found that most offenders did not trust their general practitioners enough to ask them for help, despite experiencing high levels of distress, self harming behaviour, and emotional problems.[2]

Childhood abuse and early traumatic life events are associated with increased rates of neurotic disorders, including post-traumatic stress disorder, substance misuse, self harm, and antisocial personality disorder in adulthood.[3 4] Survivors of abuse have problems in trusting others (particularly figures in authority), and both victims and perpetrators of crime commonly have feelings of low self esteem, shame, and helplessness.[5 6] Male prisoners have high rates of lifetime traumatic experiences,[2-4] and not surprisingly these "offender-victims" experience high levels of psychological distress, yet are reluctant to seek help from health professionals.

Even in the general population, only a minority of people consult their general practitioner for emotional or psychological problems, preferring instead to turn to family members or friends for help.[7] Offenders may be a particularly difficult group to engage in primary health care because most are men, and men are less likely to seek help than women. In addition, their family and social networks are often severely disrupted (if they ever existed in the first place), thus depriving them of alternative sources of help and support.

Low rates of disclosure to health professionals and reluctance to seek help have also been noted in male and female victims of sexual assault and victims of domestic violence, with men being significantly less likely to disclose traumatic and distressing early experiences than women.[8] The National Survey of Sexual Abuse and Violence in Northern Ireland found that almost half of all identified instances of abuse had never been disclosed, and health professionals were rarely chosen as the channel of disclosure.[9]

Some men in the study by Howerton and colleagues said fear of being labelled as mentally ill was a reason for not seeking help from their general practitioner.[2] For many offenders it appears that the stigma of a criminal conviction pales into insignificance compared with that of being labelled as mentally ill. This suggests that the anti-stigma campaigns run by the Royal College of Psychiatrists (such as "defeat depression"[10]) may have failed to reach the most marginalised and socially excluded members of our society, arguably those who are at highest risk of developing mental health problems and who most need to have their underlying fears and prejudices challenged.

Offenders who are seeking care but who have complex social and psychological problems, high rates of drug and alcohol misuse, low compliance with treatment, and ambivalence towards figures of authority may not view primary health care as the solution to their needs.[2] Distress and dysfunction caused by childhood experiences of abuse, neglect, and deprivation are unlikely to be rectified by a single brief consultation or a course of antidepressants, which may be all that is available in a busy inner city practice.

Seeking help in itself is not necessarily beneficial to the individual. One study of rape victims who had contact with health professionals found that about one third rated their contact with the medical system as "hurtful," mostly because of encountering negative, disbelieving, or judgmental attitudes.[11] Similarly, several offenders in the Howerton study reported that previous negative or unhelpful contact with doctors had made them more reluctant to seek help again.[2]

The relationship between a doctor and his or her patient should ideally be one of a cooperative partnership, with shared decision making in which the patient is encouraged to take the lead.[12] In mental health care, the therapeutic alliance between health professional and patient contributes to therapeutic outcome, regardless of the type of treatment.[13] However, the establishment of a therapeutic alliance may be particularly difficult with offenders, whose only experience with figures of authority has been in the context of abuse or coercion. The requirements for doctors to communicate concerns about risk to multiagency public protection panels (MAPPPs),[14] and the proposed introduction of compulsory treatment in the community may further undermine the willingness of offenders to seek help from general practitioners.

The study by Howerton and colleagues[2] reported that offenders wanted their general practitioner to listen to them, treat them with respect, provide appropriate information, and to treat them with compassion. Negative, judgmental, or rushed responses do little to enhance trust or encourage disclosure of painful experiences. In addition, the evidence emerging from research on victim support is that all community services are most effective when they are coordinated and communicate with one another.[15] Services that don't liaise effectively are unlikely to help victims or ex-offenders. The more

complex the person's psychological and social problems, the more necessary a multiagency approach becomes.

Medical intervention can help only when combined with housing support, education, access to work, and specialist input from probation services and the voluntary sector. Educational and vocational strategies aimed at enhancing social inclusion may be more effective than medical interventions in reducing feelings of shame and stigma. Such strategies can enhance the psychological health of offenders and should be considered if offenders cannot be encouraged to seek help from their general practitioners.

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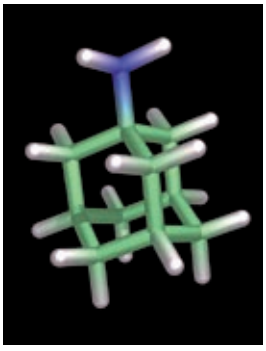
Preparing for the next flu pandemic

New clinical guidelines focus on coordinating services and standardising care



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ANALYSIS p 293

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In the past three years, the incidence of infection with the H5N1 variant of avian flu has increased in humans in southeast Asia during periods corresponding to winter and spring in the northern hemisphere.[1] More cases of H5N1 infection in humans increase the chances that the virus will adapt towards efficient transmission between humans and therefore of a flu pandemic.

The United Kingdom is well advanced in its preparations for a flu pandemic.[2] The British Infection Society, British Thoracic Society, Health Protection Agency, and Department of Health have recently developed and published provisional guidelines on the clinical management of pandemic flu.[3] These guidelines cover the clinical management of children and adults with flu during a pandemic.

In interpandemic years when influenza is circulating in the community, presentation with acute fever and new (or in chronic lung disease, worsening) cough is highly predictive of flu in adults.[4] In a pandemic, key predictive features may change as a result of altered thresholds for consultation, symptom presentation, and clinical features. If this occurs, an updated clinical definition will be released by the Health Protection Agency, informed by guidance from the World Health Organization.

Randomised controlled trials, cohort studies, and modelling studies show that antiviral agents, if given promptly, can reduce the length of illness, viral secretions, and complications; these agents may also reduce peak clinical attack rates.[5,6] The UK government has stockpiled enough oseltamivir for 25% of the population to be treated; if the clinical attack rate is higher then antivirals will have to be prioritised to risk groups.

Previous pandemics have shown that secondary bacterial complications (particularly pneumonia) have a high morbidity and mortality.[7-9] Antibiotic treatment for *Streptococcus pneumoniae, Staphylococcus aureus*, and *Haemophilus influenzae* should be considered at first consultation for adults who have serious worsening of symptoms or fever that does not start to subside after 48 hours, and for patients with chronic obstructive pulmonary disease or other severe comorbid disease (or both). Doxycycline or co-amoxiclav are recommended[3] in the community and in patients in hospital who are not severely ill.

Patients referred to hospital are likely to require management of worsening comorbid disease, such as cardiac failure or flu related pneumonia. Bilateral x ray changes in flu related pneumonia raise the possibility of primary viral pneumonia, which has a poor prognosis and should be treated as severe pneumonia.[3] Indications for transfer to critical care are no different in a pandemic, although limited resources will require effective triage and difficult ethical decisions.

In children, as in adults, fever, cough, and rhinorrhoea are cardinal symptoms of flu, but infants may simply be febrile and non-specifically unwell. Children should be given fluids, antipyretics (avoid aspirin), and antivirals—oseltamivir in liquid form can be prescribed for children aged 1-7 years.[3] Infants under 1 year are a particular problem. They have a higher risk of hospital admission and secondary bacterial infection,[10] and

oseltamivir is not indicated on the basis of central nervous system toxicity and mortality in infant rats, which is assumed to reflect immaturity of the blood-brain barrier. Infants therefore need to be assessed by a doctor, and the threshold for antibiotic treatment should be low. Those with underlying cardiac or respiratory disease, the immunocompromised, and the non-ambulant are also at increased risk of complications and should receive early antibiotics. Co-amoxiclav is recommended for children under 12 years.[3]

These clinical guideline recommendations are informed by data from seasonal flu and previous pandemics.[3] As with all pandemic plans, uncertainties are acknowledged. In particular, the virus strain and its disease potential in terms of clinical spectrum of illness, spread, and severity of illness are unknown. Furthermore, the susceptibility profile to current antiviral agents cannot be guaranteed, as discussed by Tsiodras and colleagues in this week's *BMJ*.[11] Other uncertainties relate to the epidemiology of pathogens that may have a role in secondary infections. Flu related pneumonia occurs in up to a fifth of cases; these cases are often associated with *Staphylococcus aureus* and have a worse outcome.[12 13] Community acquired strains of methicillin resistant *Staphylococcus aureus* (MRSA) are currently relatively uncommon in Europe and the UK, but are of increasing concern in the United States.[14] A change in the epidemiology of this infection in Europe could have important consequences in the event of a flu pandemic.

These guidelines will need to be revised in accordance with updated clinical and epidemiological data. Currently the pandemic alert status stands at phase 3 (human infection with a new flu virus subtype but no, or limited, human to human spread). If WHO raises the pandemic alert status to phase 5, the last of the three pre-pandemic phases (large cluster(s) of human cases and virus better adapted to humans), the guidelines will be updated.

In the meantime these guidelines will help to plan stockpiling of essential resources, coordination of services, and standardisation of care. They also provide the framework for national, regional, and local operational guidelines that take account of and detail the actions needed in the face of limited resources.

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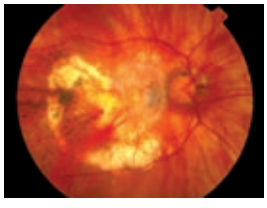
Treatments for neovascular acute macular degeneration

Drugs that inhibit vascular endothelial growth factor show real promise



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The term macular degeneration covers a spectrum of chronic and acute changes in the macular retina of both eyes and occurs in people aged 50 and above. One of the acute degenerative changes, choroidal neovascularisation, comprises an ingrowth of permeable and fragile new vessels from the choroid into the epithelial and subretinal spaces of the pigment layer,[1] stimulated by pathological secretion of vascular endothelial growth factor (VEGF). In the United Kingdom choroidal neovascularisation causes severe visual impairment or blindness in around 3.5% of people aged 75 or more.[2]

Discovery of the role of vascular endothelial growth factor led to hypotheses that blocking or neutralising this factor might yield a treatment for choroidal neovascularisation.[3] Clinicians had low expectations of success, however, because other new types of treatments had shown limited or no benefit. Moreover, the biological agents that induce blockade of the factor have many unwanted side effects. Given systemically, these drugs increase the risk of serious thromboembolic events. Given as intraocular injections they risk infection, haemorrhage, and undesirable ocular immune responses.

Despite these concerns, the absence of other effective treatments led to the vascular endothelial growth factor inhibition study in ocular neovascularisation (VISION), which provided proof of concept that intraocular inhibition of the growth factor for up to two years was feasible and safe.[4] At 12 months' follow-up, 78% of the eyes treated with repeated intravitreal injections of pegaptanib sodium (a selective antagonist of the $VEGF_{165}$ isoform of the growth factor) had visual acuity within three lines of that at baseline using Snellen charts, compared with 55% of the eyes in the control group, which had sham injections.

Competing interests: see end of editorial

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Two international multicentre controlled clinical trials (MARINA and ANCHOR) of ranibizumab for treatment of choroidal neovascularisation have now reported positive visual outcomes.[5 6] Ranibizumab is a monoclonal antibody against vascular endothelial growth factor, which inhibits all its isoforms. At 12 months' follow-up, more than 90% of eyes randomised to ranibizumab had visual acuity that remained within three lines of presenting acuity, whereas a significantly greater proportion of those randomised to placebo[5] or photodynamic therapy[6] experienced loss of acuity of three or more lines. Furthermore, around a third of eyes in the ranibizumab group had a visual acuity of Snellen 6/12 or better, an outcome that would have been thought unattainable a short while ago.

How does inhibition of vascular endothelial growth factor work? The impressive improvements in visual acuity seen in the ranibizumab trials are thought provoking. When used in oncology, inhibition of vascular endothelial growth factor leads to normalisation of the leaky, tortuous, and dilated vasculature of the tumour.[7] In choroidal neovascularisation the same action presumably restores the vasculature. Different isoforms of the growth factor probably contribute to leakiness, abnormal morphology, and fragility of the neovascular complex. Thus, ranibizumab has better outcomes than pegaptanib sodium, which inhibits $VEGF_{165}$ alone.

How long should inhibition of the growth factor continue? The VISION trials showed that two years of continuous treatment was better than one year.[4] The PIER study, in which the dosing interval for ranibizumab was increased to every three months after three initial monthly injections, yielded less satisfactory outcomes at 12 months than the MARINA and ANCHOR trials in which monthly treatments were continued for two years.[8] Furthermore, the PrONTO study, a small case series of patients in which ranibizumab was given without fixed dosing intervals but treatment was tailored to morphological parameters, resulted in 12 month visual outcomes similar to those of the major trials.[8]

What are the potential dangers of these treatments? Vascular endothelial growth factor is a survival factor for neuronal cells and a fundamental requisite for the maintenance of fenestration of the choriocapillaris, which is necessary for normal physiological functioning of the choroid itself, retinal pigment epithelium, and outer retina. Potentially, chronic inhibition of this growth factor could lead to atrophy of these tissues.[9] However, the severity of vision loss in untreated choroidal neovascularisation has to be put into perspective. The impairment in quality of life and ability to carry out normal everyday activities in patients with bilateral neovascular acute macular degeneration is equivalent to that seen in cancer and severe myocardial disease.[10] Low dropout rates in the vascular endothelial growth factor inhibition trials suggest that patients accept the potential long term risks associated with such treatment so that they can maintain vision in the short term.

What are the economic consequences for the National Health Service? A technology appraisal of pegaptanib and ranibizumab by the National Institute of Health and Clinical Excellence is due by the end of this year. The estimated annual incidence of choroidal neovascularisation is between 25 000 and 30 000 cases.[11] With pegaptanib sodium the annual drug bill alone can be expected to exceed £0.5bn (€0.75bn; $1.0bn). Substitution with ranibizumab will increase the overall cost because of the need for more frequent administration and higher unit cost (although a definitive UK price has not yet been set). Substitution with bevacizumab, the cheaper parent molecule of ranibizumab, will cost a more manageable £2m. Visual outcomes are reported to be equivalent to that of ranibizumab, but the data come from multiple case series.[12] Bevacizumab is licensed solely for treatment of colorectal cancer, does not carry a label for acute macular degeneration, and is not licensed for intraocular delivery. Retrospective case series are no substitute for outcomes measured prospectively; therefore, a controlled clinical trial of bevacizumab versus ranibizumab should be a priority for health services already struggling to meet the demands of ever ageing populations.

Competing interests: UC has been on scientific advisory boards of Novartis, Pfizer, Genaera, Jerini, and Eyetech, all of whom have proprietary interest in agents that inhibit vascular endothelial growth factor. She was a member of the VISION Trials Study Group. She has received financial assistance from some of the above for speaking engagements at conferences. JIL has been on scientific advisory boards of Novartis, Pfizer, EyeTech, Genentech, and Allergan. She was a member of the VISION, MARINA, and ANCHOR clinical trials study groups.

Provenance and peer review: Not commissioned, peer reviewed. Pfizer, the company marketing the vascular endothelial growth factor inhibitor Macugen (pegaptanib sodium), asked UC to write an editorial on the drug. She had been an investigator in trials of that agent which showed some benefit on acute macular degeneration. However, until better evidence was available she was highly sceptical about such invasive and potentially harmful treatments. She declined the offer to write an editorial funded by the Pfizer, but the suggestion gave her the idea of writing about the wider topic of vascular endothelial growth factor inhibition in acute macular degeneration.

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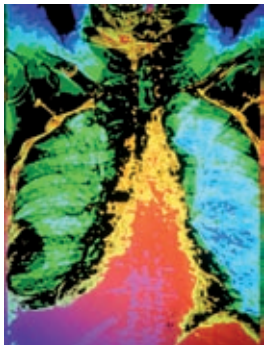
Computed tomography screening for lung cancer

Results of randomised trials are needed before recommending its adoption



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It seems logical—and appealing—that early diagnosis of lung cancer is beneficial. But simple logic can be misleading when interpreting studies on cancer screening. The central issue is that the longer survival of patients with screen detected cancers results from a combination of lead time bias, length bias, overdiagnosis bias, and true effectiveness of screening.[1]

By design, screening detects cancers earlier (lead time), but earlier detection may not change the time until death from cancer. Periodic screening will detect a large proportion of slower growing cancers because they persist longer in an asymptomatic state (length bias), and it may detect slow growing cancers that do not need treating (overdiagnosis). Without a control group, it is difficult if not impossible to distinguish between these effects, or even to be sure that screening has any true effect at all.

Despite this, early detection promises the best hope for reducing mortality due to lung cancer. The recently published results of the International Early Lung Cancer Action Program (I-ELCAP)[2] have revived hopes that effective screening measures can be developed. However, the findings of that study—that patients with lung cancers detected by computed tomography have longer survival—must be put into the context of the evidence base for lung cancer screening.[3] We should also remind ourselves of the apparent counterintuitive truth that longer survival is not equivalent to reduced mortality.

A case in point is the Mayo lung project, one of several trials of chest x ray screening performed in the 1970s. Patients in the intervention arm had higher survival rates than those in the control arm, but screening had no effect on mortality, even after nearly three decades of follow-up.[4] If this study had not included a control arm, the higher survival in patients with cancers detected by screening rather than via usual care might have prompted the inappropriate adoption of widespread chest x ray screening. Given this hindsight, will we still adopt computed tomography screening on a similar grade of evidence from the I-ELCAP study?

The publicity surrounding the I-ELCAP article[2] and the widespread encouragement to undergo screening for breast and colorectal cancers may make the public think that the issue is clear. But the 80% reduction in deaths from lung cancer predicted by the authors is open to question, for the reasons just discussed. The contrast between the 92% five year survival of patients whose lung cancers were resected and the death from lung cancer of eight untreated patients with stage I disease by five years is cited by the authors as evidence that resection offers a cure. However, this interpretation is problematic for several reasons. The sample size was small, some patients chose not to take up treatment, and case mix may have been a problem. The non-resected cancers may have been of a more aggressive histological type than the resected ones, most of which were slow growing adenocarcinomas.

Our aim is not categorically to dismiss the use of computed tomography screening for lung cancer. Currently, we are evaluating screening with simulation modelling, and we expect that screening with computed tomography will reduce mortality from lung cancer by a modest amount. But we must balance any potential (as yet unproved) benefits with the real risks of morbidity from invasive follow-up procedures. Between 13% and 50% of participants in recent computed tomography screening trials had positive (variously defined) baseline results, of which 88-97% were false positives (benign pulmonary lesions).[2 5-8] Such screening will therefore subject otherwise healthy people to follow-up examinations, including needle aspirates with risks of complications and morbidity. In a recent pilot study, 13% of people with positive computed tomography results had at least one biopsy or invasive test; more than 40% of these had benign disease.[9]

Resources devoted to lung cancer screening will not be available for other, possibly more useful, interventions to reduce mortality from lung cancer. Of course, smoking cessation alone is not a panacea; half of lung cancers are now diagnosed in former smokers, so some kind of screening for lung cancer is needed. In the future, biomarkers (such as proteomic or metabonomic patterns) could be used alone or in conjunction with an imaging based technology, such as computed tomography, to identify early stage lung cancers. In addition, genetic markers could be used to identify people at high risk for lung cancer who would benefit from more intensive screening. However, we currently have no evidence that any of these technologies help with early detection.

Where does all of this leave practising doctors and their patients? Lung cancer screening may soon be shown to be beneficial, but it would be prudent to await results of ongoing randomised studies[10 11] before recommending its adoption. We must be careful what we promise the public; evidence based science should inform policy. Recall the hasty about face after hormone replacement therapy was shown in randomised trials (as opposed to observational studies) to offer no overall benefit on mortality.[12] Such abrupt reversals degrade public trust in biomedical research at a time when scientific knowledge grows increasingly complex.

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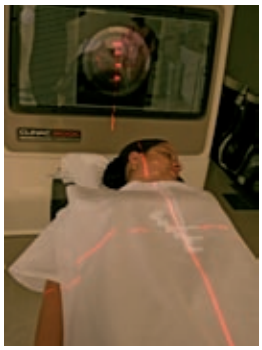
Full references 1-12 are on bmj.com

Reducing harm from radiotherapy

Healthcare systems should follow the lead developed in other high risk industries



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Like most treatments, radiotherapy has the power to heal but also to harm.[1] Worldwide, around 10 million people are newly diagnosed with cancer each year and 40-50% will receive radiotherapy.[2] In the United Kingdom, around 200 linear accelerators deliver 100 000 courses of radiotherapy in 1.5 million fractions annually; this results in roughly 4.25 million doses of radiation for cancer treatment each year (data from the Health Protection Agency (www.hpa.org.uk/) and the National Cancer Services Analysis Team (www.canceruk.net/).

Because of the hazardous nature of radiation, an extensive framework of protocols, standards, and legislation is in place to protect patients and healthcare workers.[3-6] The World Health Organization World Alliance for Patient Safety has this year taken up the challenge of making radiotherapy safer (www.who.int/patientsafety/en). It will deal with two key questions. Firstly, can standardised safety interventions be developed that reliably and consistently reduce the risk of patients being harmed by radiotherapy? Secondly, can lessons from previous errors be rapidly translated into safer health care for patients everywhere?

Despite global efforts to minimise harm from radiotherapy, cases where patients have been harmed in apparently similar circumstances are reported.[7-9] This is corrosive to public trust and confidence in services and undermines the credibility of professionals who provide health care.

In 2004, at Cookridge Hospital, West Yorkshire, a woman was prescribed 15 radiotherapy treatments for breast cancer. A crucial error was made before delivery of the first treatment, and this error was repeated for 14 treatments. This resulted in the patient receiving a higher dose of radiation than was intended, with a cumulative overdose of 2.5 times the amount prescribed. Computerised parameters had been mixed up, so that an essential treatment factor was omitted. The patient survived but her life expectancy may have been shortened.[7]

In 2006, at the Beatson Oncology Centre in Glasgow, a teenager received 19 radiotherapy treatments for a brain tumour. At the end of these treatments it was realised that each dose had been too high, in total overdosing the patient by 58%. During the first treatment it was not realised that a manual calculation needed to be applied after the computer provided the treatment plan.[8] This occurred at a time when new technology was being introduced.

In 1991 at North Staffordshire Royal Infirmary it was discovered that 1000 cancer patients had received incorrect doses of radiotherapy for nearly 10 years. When new computers were introduced in 1982 for certain cancer treatments, the comprehensive nature of the system had not been fully realised. Consequently, a manual adjustment was erroneously and repetitively made to the data, changing the dose of radiation delivered.[9] The error only came to light when technology was being updated a decade later.

On top of these well documented incidents, the National Health Service Litigation Authority (www.nhsla.com/) has reported around 150 negligence claims for radiation damage over about 30 years.

So how can we learn from these instances and what are the challenges ahead? The first major challenge is to implement new technology effectively. Technology that allows computers to be used for cancer treatments is welcome as it avoids the need for complex manual calculations. However, new technologies can be poorly implemented because staff are inadequately trained. This may introduce a whole new set of risks to patients.

The second challenge is to prevent harm to patients. Current concepts of patient safety recognise that human error is inevitable; however, harm to patients is not. Organisations need to have robust mechanisms for detecting errors quickly to ensure that patients are not harmed. Standard operating procedures are a key element of most high risk industries, such as aviation, but hardly feature in health care. In the clinical incidents described, these defence barriers were ineffective or nonexistent. Not only did errors turn into harm, the same error occurred repeatedly, affecting other patients.

The third is to put safety at the core of healthcare delivery. An organisational culture that promotes safety has distinct and consistent characteristics. These include effective organisational leadership, well designed systems and processes of care, and competent healthcare staff. Such characteristics are vital for ensuring the safety of patients.

Recognising the problem is a starting point, yet finding the solution is a challenge. There are many examples worldwide of organisations and best practices from which we can learn.[10] The UK needs to have an important role in this work. This will involve analysing information from all major radiotherapy incidents worldwide, identifying common causes, designing standard operating procedures that staff can use, and measuring progress by reduction in harm to patients.

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